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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,743	01/30/1998	JOSEPH D. ROSENBLATT	176/60192(UR)	7389

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/07/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/016,743

Applicant(s)

ROSENBLATT ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10, 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 7/19/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/016,743 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1, 3-10, 25 are pending.  
Claim 1 has been amended.  
Claims 11-24 and 26-76 have been canceled.  
Claims 1, 3-10 and 25 are under examination.
3. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection.

### ***Sequence Requirements***

5. This application contains sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2), for example those in Figure 3, and page 45, line 6-7. In order for compact prosecution, an Office Action can be performed on this application.

Art Unit: 1642

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

***Rejections Withdrawn***

6. The rejection of claims 1, 3-10 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn upon reconsideration.

***Response to Arguments***

7. The rejection of claims 1-8, 10 and 25 under 35 U.S.C. 103(a) as being unpatentable over Holzer et al (U.S. Patent 5,824,782, filed 9/15/95) and further in view of Huston et al (Meth. Enzymol. 203:46-88, 1991) is maintained.

Art Unit: 1642

The response of 7/19/02 has been carefully considered but is deemed not to be persuasive. The response states that Huston relates to single chain Fv constructs and Huston is distinguishable from the claimed complete antibody because native IgG antibodies not only contain VH and VL domains but also regions CH1, CH2, and CH3 and the antibodies of Huston not only lack constant regions of IgG but also the native conformation of such antibodies (see page 2-3 of response). In addition the response relies on the declaration of Seung-Uon Shin. The declaration has been carefully considered but is deemed not to be persuasive. The declaration states that there are significant differences with regard to the avidity, half life, and chemokine carriage which would cause scientists skilled in the field of antibody cancer therapeutics to avoid adapting single chain Fv analog technology to whole antibody cancer therapy (see page 1 of declaration). The declaration then summarizes the points of avidity, half life and chemokine carriage. The response states that that whole antibodies can carry two molecules but single chain Fv analogs carry only a single chemokine (see page 3 of declaration). In response to these arguments and the declaration, it is acknowledged that there are differences between antibodies comprising constant regions and single chain antibodies. In addition, while it is true that antibodies comprising two heavy chains and two light chain can carry two chemokines, the claims do not require this. With regard to the arguments of scientists avoiding adapting single chain antibody technology to whole antibodies, one does not have to adapt single chain antibodies as far as the characteristics discussed in the declaration to those of antibodies. The art of Holzer et al describes antibodies with chemokines at the C terminus and Huston et al

Art Unit: 1642

teach conjugation at the N terminus that does not affect binding or the activity of the chemokine, thus, in view of Holzer et al one skill in the art would conclude that it would be obvious to conjugate the chemokine to the N terminus in view of Huston et al. The only difference in the claims and Holzer is the placing of the chemokine at the N terminus, which would have been obvious in view of Huston et al.

8. The rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being unpatentable over Huston et al (Meth. Enzymol. 203:46-88, 1991), and further in view of Bacus (U.S. Patent 5,514,554, filed 10/7/93) and Holzer et al (U. S. Patent 5,824,728, filed 9/15/95) is maintained.

The response filed 7/19/02 has been carefully considered but is deemed not to be persuasive. The response states Bacus does not overcome the above-noted deficiencies of Holzer and Huston. In response to this argument, the response to Holzer and Huston has been presented above. Bacus is cited for teaching monoclonal antibodies to her2/neu conjugated to therapeutic agents which are obvious in view of Holzer and Huston.

***The following are some NEW GROUNDS of rejection***

***Claim Rejections - 35 USC § 112***

Art Unit: 1642

9. Claims 1, 3-10, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 3-10, 25 are indefinite for reciting "complete antibody" in claim 1 because the exact meaning of the phrase is not clear. Does the phrase mean "complete" in the sense of binding or having the function of the antibody such as binding or Fc mediated function, or does the antibody comprise a constant region of CH1, CH2, and CH3?

b. Claims 1, 3-10, 25 are indefinite for reciting "capable of binding" because the exact meaning of the phrase is not clear. Does the antibody bind a tumor cell associated antigen or not?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 3-10, and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite "a complete antibody". Support for the claim was not described in the response filed 7/19/02. The specification does not

Art Unit: 1642

describe a "complete antibody". The specification discloses antibodies as various types including IgG and may be monoclonal or polyclonal and be of any species origin and chimeric and include fragments (see pages 22-23). Applicant is required to provide specific support for the claimed limitation in the specification as originally filed or remove it from the claims.

### ***Conclusion***

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the



Art Unit: 1642

Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

  
SHEELA HUFF  
PRIMARY EXAMINER